

NOV 22 2000

K00 2816
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II 510(k) Summary of Safety and Effectiveness in Accordance with SMDA'90

Transonic Systems Inc.
34 Dutch Mill Rd
Ithaca, NY 14850B.
(607) 257-5300

August 31, 2000

Contact: Mark S. Alsberge, VP Medical and Regulatory Affairs

Product Name: Transonic Hemodialysis Flow Reverser

Classification name: Hemodialysis Accessories, Blood Circuit,

Gastroenterology and Urology
Class II, 78KOC
21 CFR §876.5820

SUBSTANTIAL EQUIVALENCE¹ TO:

510 (k) Number	Name	Applicant
K994306	Reverso™	MEDISYSTEMS CORP.

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, Transonic Systems Inc. intends to introduce into interstate commerce the Transonic Hemodialysis Flow Reverser which is intended to be used as part of an extracorporeal blood circuit for hemodialysis.

Material:

The Transonic Hemodialysis Flow Reverser is composed of materials that have been tested in accordance with the EN Standard 30993 and/or USP class VI and therefore suitable for the intended use of this product.

¹ The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

Substantial equivalence:

The Transonic Hemodialysis Flow Reverser is similar in materials, form and intended use to the Reverso™ currently marketed by Medisystems Corp. and cleared under K994306. There are no new issues of safety or effectiveness raised by Transonic Hemodialysis Flow Reverser.

Safety And Effectiveness:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; physical testing, visual examination (in process and finished product). The ANSI/AAMI standard "*American National Standard for Hemodialyzer Blood Tubing*" RD17- 1994 was followed for the design and will continue to be followed for the production and quality assurance testing of this device.

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control cGMP"s.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2000

Mr. Mark S. Alsberge
VP Medical and Regulatory Affairs
Transonic Systems Incorporated
34 Dutch Mill Road
ITHACA NY 14850

Re: K002816
Transonic Hemodialysis Flow Reverser
Dated: September 07, 2000
Received: September 11, 2000
Regulatory Class: II
21 CFR §876.5820/Procode: 78 KOC

Dear Mr. Alsberge:

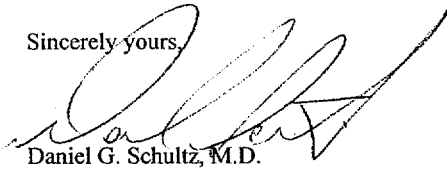
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002816

Device Name: Transonic Hemodialysis Flow Reverser

Indications for Use:

The Transonic Hemodialysis Flow Reverser is indicated for use as part of an extracorporeal blood circuit for hemodialysis when the reversal of flow will be needed to make access flow and/or recirculation measurements during the patient's hemodialysis treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Syvan
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K002816

Prescription Device YES

(Posted July 1, 1998)

(Optional Format 3-10-98)